**Study Title: Evaluation of 0.18% HA Emulsion Eyedrop for Moderate to Severe Dry Eye**

1. **Participants**

*Phase 1*

Screened n= 43

Screen failure n=3

Enrolled n= 15

Included in Analysis n= 15

*Phase 2*

Screened n= 43

Screen failure n=3

Phase 1 n=15

Enrolled Phase 2 n= 25

Included in Analysis n= 40

1. **Baseline Characteristics**

Table 1 – Gender and Age of Study Population

|  |  |  |  |
| --- | --- | --- | --- |
|  | P1 & 2 | P2 only | All Phase 2 |
| N | 15 | 25 | 40 |
| Gender |  |  |  |
| Female | 10 (67%) | 15 (60%) | 25 (62.5%) |
| Male | 5 (33%) | 10 (40%) | 15 (37.5%) |
| Age (years) |  |  |  |
| Mean | 55.4 | 51.1 | 52.7 |
| Std. Dev | 10.1 | 15.7 | 13.9 |

1. **Outcome Measures**

*Primary Outcome Measures*

 Table 2 - Tear film characteristics (NIBUT)

|  |  |  |
| --- | --- | --- |
| NIBUT (s) | Baseline | 1-Month |
| N | 80 | 80 |
| Mean | 7.36 | 8.46 |
| Median | 4.90 | 6.71 |
| Std. Dev | 5.95 | 6.96 |

Table 3 – Subjective Acceptance for Comfort (100-point VAS)

|  |  |  |
| --- | --- | --- |
| Comfort | Baseline | 1 -Month |
| N | 40 | 40 |
| Mean | 44.3 | 62.1 |
| Median | 48.0 | 63.0 |
| Std. Dev | 20.6 | 24.4 |

1. **Adverse Events**

Two adverse events were reported during the study. Both were non-serious and non-ocular.

Table 4 - Adverse Events

|  |  |  |
| --- | --- | --- |
| **Number of Participants affected** | **Event** | **Current status** |
| 1 | Sore Throat  | Resolved |
| 1 | Migraine | Resolved |